

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,)	
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)	
Plaintiff,)	No. 05-CR-10102 JLT
)	
v.)	
)	
)	
JOHN BRUENS, MARY STEWART,)	
MELISSA VAUGHN, and)	
MARC SIROCKMAN,)	
)	
)	
Defendants.)	
)	

**DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE
TESTIMONY BY SAUL N. MALOZOWSKI, M.D., PH.D.**

The Government alleges that in March 1999, in order to counter lagging first quarter sales, four former employees of Serono Laboratories, Inc. (“Serono” or the “Company”) arranged for doctors who wrote thirty prescriptions of the Company’s AIDS wasting drug, Serostim, to receive an all expense-paid trip to a medical conference in Cannes, France. These allegations have nothing whatsoever to do with the science or regulatory approval of Serostim, the efficacy of competing drugs and other AIDS treatments, or the scientific and medical aspects of the AIDS virus. And yet, these are the very topics on which the Government intends to elicit testimony from Saul Malozowski, M.D., Ph.D., a scientific witness with no direct knowledge of the matters at issue in this case.¹

¹ We are filing this motion *in limine* at this time because defendants just received from the Government on Friday, April 6th at 6:11 p.m., an exhibit list that contains documents relating to testimony that the Government apparently intends to elicit from Dr. Malozowski. Based on the Court’s remarks at the status conference on

Dr. Malozowski is a scientific expert and his testimony should not be allowed in a case that has nothing to do with science. Even as a fact witness, his testimony is entirely extrinsic to the *quid pro quo* alleged in the Indictment and would not, therefore, be helpful to trier of fact. To the extent that he may have relevant testimony on any matters of historical fact, the Government can introduce such testimony through other Government witnesses, including doctors, cooperating witnesses, and the *qui tam* relators who originated this case. Allowing Dr. Malozowski to testify either as an expert or as a fact witness to the same facts as these other witnesses would impermissibly bolster the testimony of those fact witnesses, increasing the risk of reversible error. For these reasons, Dr. Malozowski's testimony is both inadmissible and unnecessary.

I. Dr. Malozowski's Testimony Is Extrinsic To The Conspiracy Charged In The Indictment And Should Not Be Allowed.

At the pretrial conference on December 18, 2006, the Government proffered that Dr. Malozowski will offer "very key evidence with respect to the Government's case." Tr. of Pretrial Conference on December 18, 2006 at 11. According to the Government, Dr. Malozowski will testify that:

- Serostim was given accelerated approval by the FDA in August 1996;
- Serostim was launched in fall of 1996 and early 1997;
- When Serostim came on the market, a twelve-week course of treatment was priced at \$21,000;
- Protease inhibitors, also referred to as the "HAART" regimen or "AIDS cocktails," also came onto the market between 1996 and 1998;

January 16, 2007, discussed in greater detail herein, defendants did not expect the Government to call Dr. Malozowski. Although the Government has yet to submit its witness list, we were concerned about waiting to file the motion, given the imminent trial date.

- As early as 1997, the market for Serostim “dropped out”; and
- Lipodystrophy was another AIDS-related condition that could be treated with Serostim.

Id. at 9-12. Dr. Malozowski also testified at length in the grand jury about many scientific and technical matters, including studies done to support Serostim’s regulatory approval by the U.S. Food and Drug Administration (“FDA”), objections to Serostim’s approval, Serostim’s clinical side effects, clinical data on lean body mass and AIDS survival rates, the clinical landscape of AIDS and AIDS treatment from as early as 1993, Serostim’s Phase IV study and approval process, and changes in how AIDS presented in patients over time.

As this Court has already recognized, this testimony is outside the scope of the conspiracy charged in the Indictment and should not be allowed. Specifically, this Court has instructed that:

If anybody thinks there is going to be expert testimony along the lines that because business was bad, this is motivation for starting a conspiracy to juice up sales, I am not going – *there is not going to be any such expert testimony.*

I can’t conceive the government would even try to offer such testimony.

* * *

In other words, what I think is legitimate is a certain amount of context to establish the conspiracy. Business is lousy. The guy gets all excited. He is going to the Boston Harbor Hotel. Four people in the room, let’s do something. And they have this, you know millions of dollars worth of sales in six days or whatever, however it was going to be. And what motivated them was the fact that business was no as good as it should be. That comes in, I think. That is okay. (emphasis added).

Tr. of Hearing on January 16, 2007 at 4-5. Therefore, based on the Government's proffer, any testimony Dr. Malozowski may offer is irrelevant to the charged conspiracy.² The Government maintains that Dr. Malozowski's testimony will necessarily assist the trier of fact in understanding why there was pressure for the defendants to "get their numbers up." But, whether he is testifying as an expert or as a fact witness, Dr. Malozowski cannot possibly know anything about the Boston Harbor Hotel meeting, Serostim sales, alleged discussions between co-conspirators, or any other testimony the Court described above as potentially providing context for understanding the alleged conspiracy. Accordingly, his testimony should not be allowed.

Moreover, the Government has indicated that other, non-expert witnesses, including doctors, such as David Condolucci, M.D. and Ralph Liporace, M.D., and former Serono employees, among them Ray Hudgens, would also be called to provide additional context for the jury. Tr. of Pretrial Conference on December 18, 2006 at 27. For example, the details surrounding Serostim's approval by the FDA and its launch in 1996 and 1997 are historical facts that are easily offered through Serono employees involved in that process or many of the 2.5

² The Government has already conceded that many of the matters Dr. Malozowski may testify to are outside the scope of the charges in this case. For example, Dr. Malozowski testified at length in the grand jury about a medical condition known as lipodystrophy and, at the December 18th pretrial conference, the Government offered the theory that Serono sought to promote Serostim for the treatment of lipodystrophy to offset the loss of Serostim's market share to protease inhibitors. When defense counsel brought to the Court's attention the fact that prescribing Serostim for lipodystrophy is an off-label use of the drug, the Government conceded that this "is not an off-label case and we are not going to introduce that evidence." Tr. of Pretrial Conference on December 18, 2006 at 14.

The Government also indicated that it intended to offer Dr. Malozowski as an expert in the FDA approval process generally and Serostim's FDA approval in particular, but again later conceded that the defendants were not involved with that process, they were merely employed at Serono during Serostim's initial launch, stating that "[a]lthough [the defendants] weren't involved in the actual submission of the NDA to the FDA, Mary Stewart and John Bruens particularly were with the company at that time and were particularly – and even Melissa Vaughn was with the company when the drug was launched." *Id.* at 9-10. Serostim's FDA approval occurred from 1996 to 1997, while the alleged kickbacks that are the subject of the Indictment occurred almost two years later, in 1999. Even if there were some temporal connection, the mere fact that three of the defendants were employed at Serono while the drug was being submitted for FDA approval hardly supplies the degree of relevance needed to render Dr. Malozowski's testimony relevant to the charged conspiracy.

million pages of material produced by the Company to the Government. Similarly, the state of Serostim sales and the impact thereon by competing drugs or protease inhibitors—evidence the Government cites as “very key” to its case—can be established through any number of Serono employees or from sales tracking documents also in the Government’s possession.³ Likewise, the cost details of a course of Serostim treatment are historical facts that Government witnesses, including Mr. Hudgens and Drs. Condolucci and Liporace, can provide in their testimony.

II. The Admission of Dr. Malozowski’s Testimony Creates A Substantial Risk of Prejudice And May Constitute Reversible Error.

Allowing a scientific expert like Dr. Malozowski to testify in this case—when he has such limited knowledge, if any, regarding the matters at issue to the charged conspiracy—creates a substantial risk of prejudice that the jury will give inappropriate weight to testimony with limited relevance. “When the tenor of [an] expert’s testimony is closely aligned with the facts of the case, the testimony may create an improper implication that [an expert] believes the government’s witness to be credible and the defendant to be guilty.” *United States v. Amuso*, 21 F.3d 1251, 1263 (2d Cir. 1994) (citations and quotations omitted). This Circuit has echoed that sentiment, recognizing that when the Government seeks to bolster its theory by admitting evidence through an expert, “the risk of unfair prejudice is real. By appearing to put the expert’s stamp of approval on the Government’s theory, such testimony might unduly influence the jury’s own assessment of the inference that is being urged.” *United States v. Montas*, 41 F.3d 774, 784 (1st Cir. 1994) (expert testimony regarding aliases should have been excluded as within province of testimony an “average juror [could] assess intelligently”); *see also United States v. Gaines*, 170 F.3d 72, 80 (1st Cir. 1999) (“Expert testimony is not admissible . . . on matters that are

³ It also appears that a sales or marketing expert would be better qualified to testify concerning these topics than a scientific expert such as Dr. Malozowski.

readily intelligible and may . . . create unfair prejudice by appearing to put the expert's stamp of approval on the government's case.") (internal quotations and citation omitted).

The Government's repeated assertion that this testimony is necessary "context" does not salvage the proffered testimony because such "context" may constitute reversible error.⁴ In *United States v. Cruz*, the Second Circuit reversed a defendant's conviction because the district court improperly allowed a law enforcement officer to testify about typical drug trafficking operations in the Washington Heights area and the function of a broker in drug transactions. The agent's expert testimony was repeatedly referenced in the Government's summation, where the Government argued that facts offered by other witnesses were consistent with the expert's description of drug operations and the role of brokers and intermediaries. 981 F.2d 659, 660-62 (2d Cir. 1992). The Government argued on appeal that the agent's testimony was necessary context that helped the jury understand other fact witness testimony about the use of intermediaries and brokers in drug trafficking that was beyond the knowledge and understanding of an average juror. The Second Circuit disagreed, however, reversing the defendant's convictions and "reaffirm[ing] . . . the principle that the credibility of a fact-witness may not be

⁴ This is particularly true here because it is unclear precisely what "context" the Government intends to offer, as the Government's representations about its position on Serostim's effectiveness appear to keep changing. At the December 18th conference, the Government originally articulated the theory that "there was no market out there because these patients weren't suffering from AIDS wasting [in 1999]," and that the alleged crimes occurred in a "context where the AIDS wasting was disappearing in this country – thank God – and there were not patients that were suffering from this condition" Tr. of December 18, 2006 Pretrial Conference at 19, 23. Later in the same conference, however, the Government appeared to change this position, offering the alternate theory:

We don't say there was no AIDS wasting. There is AIDS wasting. It was an AIDS defining condition. However, it declined substantially with the onset of protease inhibitors and the HAART cocktail. There continues to this day to be patients that suffer from AIDS wasting for whom this drug is lifesaving . . . We do not say it was a fake disease. We do not say it was a false disease. Simply that the prevalence and incidence of the disease dramatically decreased as a result of the onset of new medications.

Id. at 27-28. Extraordinarily, the Government went as far as to indicate that "[w]e are going to say quite frankly that for a small percentage of patients [Serostim] was lifesaving. The drug for the condition for which it was approved was perfectly appropriate." *Id.* at 32.

bolstered by arguing that the witness's version of events is consistent with an expert's" testimony. *Id.* at 663. In *United States v. Gaines*, this Circuit echoed that principle, stating that expert testimony may "create unfair prejudice by appearing to put the expert's stamp of approval on the government's case." 170 F.3d at 80⁵; *see also Amuso*, 21 F.3d at 1256 ("A district court may commit manifest error by admitting expert testimony where the evidence impermissibly mirrors the testimony offered by fact witnesses . . ."). As in *Cruz*, Dr. Malozowski should not be permitted to offer "context" under the guise of expert testimony that bolsters the same fact testimony the Government easily can (and likely will) offer through other fact witnesses and documents.

Moreover, the risk of such prejudice is real even if Dr. Malozowski is not specifically offered as an expert because his scientific background and stature create the risk of bolstering in the jury's eyes any testimony he might give. The fact that he has such limited knowledge about the alleged conspiracy itself makes that risk even greater. Because of these risks and the limited use and relevance of any testimony Dr. Malozowski could offer, whether as an expert or as a fact witness, that testimony should not be excluded from the upcoming trial.

⁵ Although it held that the expert testimony allowed in that case was improper, the *Gaines* court held that any error caused was harmless because the defense failed to object, forcing the Court of Appeals to review for plain error only. The Circuit made clear that "[h]ad the defense objected on the express grounds that this testimony was not a proper subject of expert testimony . . . or was unfairly prejudicial . . . it might well have been error for the court to have allowed [the expert testimony]." *Id.* at 80-81.

CONCLUSION

Dr. Malozowski's testimony is largely scientific testimony that falls outside the scope of the central question at issue in this case: did the defendants offer a *quid pro quo* to doctors who increased their prescriptions of Serostim in March 1999. To the extent that portions of Dr. Malozowski's proffered testimony are relevant to the charges in this case, the Government has acknowledged that it will offer other fact witnesses on those subjects, rendering testimony by a scientist with little direct knowledge of the conspiracy charged unnecessary and increasing the risk of prejudice by bolstering that witness testimony and creating reversible error. It is precisely the type of expert testimony that this Court has indicated it will not permit in this case. Accordingly, Dr. Malozowski should not be allowed to testify.

Respectfully submitted,

**JOHN BRUENS, MARY STEWART,
MELISSA VAUGHN and MARC SIROCKMAN,**

By their undersigned attorneys.

/s/ Adam S. Hoffinger
Adam S. Hoffinger
Counsel for Melissa Vaughn

/s/ Mark A. Berman
Mark A. Berman
Counsel for Mary Stewart

/s/ Thomas McC. Souther
Thomas McC. Souther
Counsel for John Bruens

/s/ Tracy A. Miner
Tracy A. Miner
Counsel for Marc Sirockman

Dated: April 9, 2007

REQUEST FOR ORAL ARGUMENT

Defendants respectfully request oral argument at the final pretrial conference on Thursday, April 12, 2007 to assist the Court in reaching its decision on this motion.

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Counsel for Melissa Vaughn

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Dated: April 9, 2007

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing motion was filed electronically in compliance with ECF procedures on this 9th day of April 2007.

/s/ James M. Sullivan
James M. Sullivan